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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2014-0055]

Monsanto Company; Availability of Preliminary Finding of No Significant Impact and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Soybean Genetically Engineered for Resistance to Lepidopteran Insects

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has reached a preliminary decision to extend our determination of nonregulated status of soybean event MON 87701 to soybean event MON 87751 in response to a request from the Monsanto Company. Soybean event MON 87751 has been genetically engineered for resistance to lepidopteran insects, including resistance to fall armyworm beyond that provided to soybean event MON 87701. We are making available for public comment our preliminary finding of no significant impact for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to

<http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0055>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2014-0055, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Monsanto Company extension request, our finding of no significant impact, our preliminary determination, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0055> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents and any comments we received regarding our determination of nonregulated status of the antecedent organism, MON 87701 soybean, can be found at <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0038>. Supporting documents and any comments we received regarding our determination of nonregulated status of MON 89034 corn, a referenced organism for this action, can be found at <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0030>. Combined supporting documents regarding our determination of nonregulated status for the referenced organism MON 15985 cotton can be found on the APHIS Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS Petition Number 00-342-01p. Supporting documents may also be found on the APHIS Web site for MON 87751 soybean (the organism under evaluation) under APHIS Petition Number 13-337-01p, MON 87701 soybean (the antecedent organism) under APHIS Petition Number 09-082-01p, and MON 89034 corn (a referenced organism) under APHIS Petition Number 06-298-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851-3885, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms (GE) and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

In a notice¹ published in the Federal Register on October 12, 2011 (76 FR 63279-63280, Docket No. APHIS-2011-0038), APHIS announced our determination of nonregulated status of

¹ To view the notice, our determination, supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0038>.

soybean (Glycine max) designated as event MON 87701, which was genetically engineered for lepidopteran resistance. APHIS has received a request for an extension of a determination of nonregulated status of soybean event MON 87701 (APHIS Petition Number 09-082-01p) to soybean designated as event MON 87751 (APHIS Petition Number 13-337-01p) from the Monsanto Company (Monsanto) of St. Louis, MO. MON 87751 soybean expresses resistance to lepidopteran pests similar to that of MON 87701 soybean, with the exception of increased resistance to fall armyworm (Spodoptera frugiperda). In its request, Monsanto stated that this soybean is similar to lepidopteran-resistant soybean event MON 88701 and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, soybean event MON 87751 soybean has been genetically engineered to express two Bacillus thuringiensis proteins (Cry1A.105 and Cry2Ab2) that confer resistance to certain lepidopteran pests of soybeans. The antecedent organism, MON 87701 soybean, was similarly genetically engineered to express the B. thuringiensis Cry1Ac insecticidal protein. The Cry1A.105 and Cry2Ab2 expressed in MON 87751 soybean are both similar to the Cry1Ac protein expressed in MON 87701 soybean. Based on the information in the request, we have concluded that soybean designated as event MON 88751 is similar to soybean designated as event MON 88701. Soybean event MON 87751 is currently regulated under 7 CFR part 340.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS evaluates the plant pest risk of the article. In section 403 of the PPA, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic

plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS completed a plant pest risk assessment (PPRA) on the antecedent organism, MON 87701 soybean, in which we concluded that MON 87701 soybean is unlikely to present a plant pest risk. MON 87751 soybean differs from MON 87701 soybean in the proteins expressed, specifically, Cry1A.105 and Cry2Ab2 are expressed in MON 87751 while only Cry1Ac is expressed in MON 87701. However, the activity spectra are quite similar. APHIS has evaluated Cry1A.105 and Cry2Ab2 when expressed in corn and cotton (MON 89034 and MON 15985, respectively). In the PPRA's that APHIS completed for MON 89034 corn and MON 15985 cotton, we concluded that the organisms did not pose a plant pest risk. As mentioned previously, the Cry1A.105 and Cry2Ab2 expressed in MON 87751 soybean are together similar to the Cry1Ac protein expressed in MON 87701 soybean, and APHIS has concluded that the increased activity toward fall armyworm from the proteins expressed in MON 87751 soybean is unlikely to affect the plant pest risk of MON 87751 soybean. Furthermore, the Environmental Protection Agency reviewed the safety of Cry1A.105 and Cry2Ab2 in corn and concluded that adverse effects will not occur to nontarget organisms. Therefore, based on our PPRA's for MON 87701 soybean, MON 89034 corn, and MON 15985 cotton, the similarity between MON 87751 soybean and MON 87701 soybean, the limited difference in activity spectra between MON 87751 soybean and MON 87701 soybean, and other information, APHIS has concluded that Cry1A.105 and Cry2Ab2 in MON 87751 soybean are unlikely to pose a plant pest risk and that MON 87751 soybean is unlikely to pose a different plant pest risk than MON 87701.

APHIS also prepared an environmental assessment (EA) for the antecedent organism MON 87701 soybean based on our analysis of data submitted by Monsanto, a review of other scientific data, and field tests conducted under APHIS oversight. The EA was prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the determination of nonregulated status soybean event MON 87701. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

APHIS has carefully examined the existing NEPA documentation completed for MON 87701 soybean and has concluded that Monsanto's request to extend a determination of nonregulated status to MON 87751 soybean encompasses the same scope of environmental analysis as MON 87701 soybean. Therefore, based on the similarity of MON 87751 soybean to MON 87701 soybean, APHIS has prepared a preliminary finding of no significant impact (FONSI) on MON 87751 soybean using the EA prepared for MON 87701 soybean. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of soybean event MON 87751 and it would continue to be a regulated article, or (2) make a determination of nonregulated status of soybean event MON 87751 soybean. APHIS' preferred alternative is to make a determination of nonregulated status of soybean event MON 87751.

APHIS has analyzed information submitted by Monsanto, references provided in the extension request, peer-reviewed publications, and information in the EA of the antecedent

organism MON 87701 soybean. APHIS has also analyzed information in the PPRA for the antecedent organism MON 87701 soybean, information in the PPRA for MON 89034 corn and MON 15985 cotton, the limited difference in activity spectra between MON 87751 soybean and the antecedent organism MON 87701 soybean, and other information. Based on APHIS' analysis of this information, the similarity of MON 87751 soybean to the antecedent organism MON 87701 soybean, our conclusion that the Cry1A.105 and Cry2Ab2 in MON 87751 soybean are unlikely to pose a plant pest risk, and our conclusion that MON 87751 is unlikely to pose a different plant pest risk than MON 87701, APHIS has determined that soybean event MON 87751 is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of soybean event MON 87701 to soybean event MON 87751, whereby soybean event MON 87751 would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the Federal Register announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of soybean event MON 87701 to soybean event MON 87751.

APHIS will accept written comments on the FONSI regarding a determination of nonregulated status of soybean event MON 87751 for a period of 30 days from the date this notice is published in the Federal Register. The FONSI, as well as the extension request, supporting documents, and our preliminary determination for soybean event MON 87751, are available for public review as indicated under ADDRESSES and FOR FURTHER

INFORMATION CONTACT above. Copies of these documents may also be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments will be available for public review. After reviewing and evaluating the comments, if APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further Federal Register notice will be published announcing the final regulatory determination regarding soybean event MON 87751.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of August 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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